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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,623	09/14/2000	Dennis Cherek	D0188/7125	8712

7590 05/16/2002

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,623

Applicant(s)

CHEROK ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-21 and 29-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed February 14, 2002 (Paper #7) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Applicant is requested to furnish copies of each reference or at least each non U.S. patent reference with the response to this office action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 14-17, 20, 21, 37-39, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Eldridge et al. WO 98/49967.

Eldridge et al. discloses an implantable device for repairing tissue or muscle defects comprising a layer of repair fabric made of polypropylene having interstices, barrier layer made of PTFE that covers the entire layer of repair fabric, stitches connecting both layers, and a peripheral barrier that inhibits adhesions with tissue. The peripheral barrier is formed by melting the middle layer of the repair fabric to the PTFE

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barrier layer. Note that the entire surface of the middle layer of the implant is melted to the PTFE layer and resolidified which encompasses the specific limitations of claims 4, 37, and 42) regarding a peripheral edge or outer margin being melted and resolidified (see page 5, lines 3-13).

With regard to claims 16, 17 and 44, stitches are described for attaching the barrier layer and fabric layer to tissue wherein the stitches are disposed slightly inward of the edge (see lines 1-5 of page 8 as well as lines 11-12 of page 7).

With regard to claim 39, a non-uniform thickness is disclosed in page 5, lines 7-9.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 19, 45-48, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above in view of Sharber et al. US PN 6,075,180.

Eldridge et al. meets the limitations of claims 18, 19, and 45 but lacks the express disclosure of using PTFE stitches or sutures. Sharber et al. teaches the well-known use of PTFE for suture material because of PTFE's low reactivity in the body.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute PTFE sutures, as taught by Sharber et al., for the sutures

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disclosed by Eldridge et al. in order to provide a material unlikely to react negatively in the body.

6. Claims 49-52 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above in view of Sharber et al. US PN 6,075,180 as applied to claims 18, 19, 45-48, and 53 above and in further view of Darois et al. US PN 6,258,124.

Neither Eldridge et al. or Sharber et al. expressly disclose the particular features of the stitch pattern of claims 49-52 or combination of bite region and stitches of claims 54-59. However, Darois et al. teaches in Figure 1 a repair patch having a plurality of connecting stitches following a predetermined shape of the outer perimeter, as well as a plurality of stitches arranged in a concentric pattern wherein at least one series of stitches is disposed slightly inward of the peripheral edge. Furthermore, with regard to claims 54-59, the outer margin is reinforced by the stitches to form a bite region between the outermost stitch series and outer peripheral edge. Lines 32-59 of column 4 teach that the stitch pattern is beneficial to prevent separation of the barrier layer and fabric layer after implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention disclosed by Eldridge et al. to include the PTFE stitches as taught by Sharber et al. and furthermore, use the concentric pattern as taught by Darois et al. in order to securely join the fabric layer and barrier layer to prevent separation after implantation.

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7. Claims 5-7, 29-36, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above and in further view of Pajotin et al. US PN 6,368,541.

Eldridge et al. meets the limitations of claims 5-7, 29-36, and 40-41 except Eldridge et al. does not specifically disclose an outwardly tapered peripheral barrier. However, Pajotin et al. teaches an implantable prosthesis for repairing a muscle or tissue defect having a tapered peripheral edge to assist implantation (see figure 2 and line 62 of column 1 through line 2 of column 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Eldridge et al. to include a tapered edge as taught by Pajotin et al. in order to assist implantation of the device into the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

WHM

WHM

May 13, 2002

Paul B. Prebille
Paul B. Prebille
Primary Examiner